

Attorney Docket No.: DEX0499US.NP
Inventors: Fan et al.
Serial No.: 10/593,799
Filing Date: August 6, 2007
Page 9

REMARKS

Claims 1, 2, 5, 6, 8, 11, 13, 15-17, 21, 22, 24, 26-28, 30, 34-36, 39, 40, 43, 44, 48-52, 56, 58, 62, 67, 68 and 71 are pending in the instant application. Claims 24, 26, 34-36, 39-40, 43-44, 48-49, 52, 56, 58, 62, 67-68 and 71 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants herein. Claims 1, 2, 5, 6, 8, 11, 13, 15-17, 21, 22, 27, 28, 30, 50 and 51 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed May 6, 2009. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice nonelected claims. Applicants reserve the right to file a divisional application to this subject matter.

II. Sequence Requirements

Applicants are submitting herewith a replacement paper copy and CRF copy of the Sequence Listing inclusive of the sequences

Attorney Docket No.: **DEX0499US.NP**
Inventors: **Fan et al.**
Serial No.: **10/593,799**
Filing Date: **August 6, 2007**
Page 10

set forth at page 88, lines 6-7. A statement in accordance with 37 C.F.R. 1.821-1.825 is provided herewith.

Applicants have also amended the specification herein at page 88 to include the Sequence Identifier for this sequence.

No new matter is added by these amendments and entry is respectfully requested.

III. Rejection of Claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51 under 35 U.S.C. 112, first paragraph

Claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner suggests that the specification lacks complete deposit information for the deposit of Lng105 antibodies PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629.

Applicants respectfully traverse this rejection.

Applicants believe that the statement which the Examiner suggests to be required regarding deposit to meet the enablement requirements of 35 U.S.C. 112, first paragraph is made at page 102 of the instant application. On page 102, a table entitled ATCC Deposits is provided listing PTA-5878, PTA-5879, PTA-6146,

Attorney Docket No.: **DEX0499US.NP**
Inventors: **Fan et al.**
Serial No.: **10/593,799**
Filing Date: **August 6, 2007**
Page 11

PTA-6147 and PTA-6629 as well as their deposit dates. Following this table in the instant specification, it is stated that:

These deposits were made under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure and the Regulations there under (Budapest Treaty). This assures maintenance of viable cultures for 30 years from the date of deposit. The organisms will be made available by ATCC under the terms of the Budapest Treaty, and subject to an agreement between diaDexus, Inc. and ATCC, which assures permanent and unrestricted availability of the progeny of the cultures to the public upon issuance of the pertinent U.S. patent or upon laying open to the public of any U.S. or foreign patent application, whichever comes first, and assures availability of the progeny to one determined by the U.S. Commissioner of Patents and Trademarks to be entitled thereto according to 35 USC §122 and the Commissioner's rules pursuant thereto (including 37 CFR §1.14 with particular reference to 886 OG 638).

The assignee of the present application has agreed that if the cultures on deposit should die or be lost or destroyed when cultivated under suitable conditions, they will be promptly replaced on notification with a viable specimen of the same culture. Availability of the deposited strains are not to be construed as a license to practice the invention in contravention of the rights granted under the authority of any government in accordance with its patent laws. The making of these deposits is by no means an admission that deposits are required to enable the invention

These paragraphs of the specification include statements that:

Attorney Docket No.: **DEX0499US.NP**
Inventors: **Fan et al.**
Serial No.: **10/593,799**
Filing Date: **August 6, 2007**
Page 12

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for furnishing of a sample of the deposited material, whichever is longest; and

(d) the deposits will be replaced if they become nonviable or non-replicable.

Further, Applicants have amended the above in accordance with the Examiner's suggestion to include the complete name and address of the depository.

However, in an earnest effort to advance the prosecution of this case and in accordance with the Examiner's suggestion, Applicants are providing herewith an Affidavit by Attorney of Record Kathleen A. Tyrrell stating that the deposit of antibodies PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629 has been accepted by an International Depository Authority under the provision of the Budapest Treaty and that all restrictions upon

Attorney Docket No.: **DEX0499US.NP**
Inventors: **Fan et al.**
Serial No.: **10/593,799**
Filing Date: **August 6, 2007**
Page 13

public access to the deposited material will be irrevocably removed upon the grant of a patent on this application.

Further, with respect to deposits of PTA-6146, PTA-6147 and PTA-6629, this Affidavit includes a verified statement that the deposited material is identical to the biological material described in the specification and was in the applicants' possession at the time the application was filed.

Withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims under 35 U.S.C. 102(b) and 103(a)

Claims 1-2, 5-6, 8, 11, 15-17 and 21-22 have been rejected under 35 U.S.C. 102(b) as being anticipated by Keolsch et al. (WO 98/22597).

Claims 1-2, 5-6, 8, 11, 13, 15-17, 21-22, 27-28, 30 and 50-51 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Keolsch et al. (WO 98/22597) in view of Devaux et al. (U.S. Patent 6,824,780).

The Examiner suggests that the antibodies of Keolsch et al. would compete for the same epitopes recognized by the antibodies having ATCC accession numbers PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629 and would necessarily have the recited binding properties of claims 6, 15-17 and 21-22. The Examiner suggests

Attorney Docket No.: **DEX0499US.NP**
Inventors: **Fan et al.**
Serial No.: **10/593,799**
Filing Date: **August 6, 2007**
Page 14

that one of ordinary skill in the art would reasonably conclude that the Keolsch et al. antibodies would possess the same structural and functional properties as those of antibodies that are identical to the claimed antibodies.

Applicants respectfully disagree.

At pages 8-9 of Keolsch et al., they teach that napsin specific antiserum was produced using an 18 amino acid epitope of Napsin A which was synthesized as a multiple antigenic peptide (MAP) on a poly-lysine backbone by the Molecular Biology Resources Facility. Keolsch et al. teach that this epitope (MKSGARVGLARARPRG) was common to both napsin A and B.

In contrast, antibodies produced by a hybridoma of American Type Culture Collection accession number PTA-5878, PTA-5879, PTA-6146, PTA-6147 and PTA-6629 were generated by immunization with Lng105 recombinant proteins SEQ ID NO:1 or SEQ ID NO:2. See teachings at page 89 of the instant specification. SEQ ID NO:1 is 419 amino acids in length while SEQ ID NO:2 is 438 amino acids in length. As taught at page 12 of the instant application, Applicants believe this is the first time antibodies specific to Lng105 have been generated against a full length Lng105 protein (non-peptide) and used in an ELISA to detect Lng105 in a bodily fluid to determine the presence of cancer.

Attorney Docket No.: **DEX0499US.NP**
Inventors: **Fan et al.**
Serial No.: **10/593,799**
Filing Date: **August 6, 2007**
Page 15

MPEP 2112 and the case law are clear; "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

It does not follow by scientific reasoning that the polyclonal antiserum of Keolsch et al. raised against a short 18 amino acid peptide fragment will necessarily bind the same epitopes as antibodies generated by immunization with full length Lng105 recombinant proteins SEQ ID NO:1 or SEQ ID NO:2. Nor would the antibodies of Keolsch et al. necessarily compete for binding to the same epitopes as antibodies generated by immunization with full length Lng105 recombinant proteins SEQ ID NO:1 or SEQ ID NO:2.

Applicants respectfully disagree with the Examiner that one of ordinary skill in the art would reasonably conclude that the Keolsch et al. antibodies raised against a short 18 amino acid peptide fragment would possess the same structural and functional

Attorney Docket No.: **DEX0499US.NP**
Inventors: **Fan et al.**
Serial No.: **10/593,799**
Filing Date: **August 6, 2007**
Page 16

properties as the claimed antibodies. As evidenced by data presented in Example 1 of the specification beginning at page 86, antibodies generated by immunization with full length Lng105 recombinant proteins SEQ ID NO:1 or SEQ ID NO:2 are highly specific for Lng105 and demonstrate excellent sensitivity for detection Lng105. Such is not the case for the polyclonal antiserum of Keolsch et al. raised against an epitope common to both napsin A and B. Clearly such antibodies do not exhibit the same selective binding properties as the instant claimed antibodies.

Thus, neither the express, implicit, or inherent disclosure of Keolsch et al. anticipates or renders obvious the instant claimed antibodies.

Teachings of Devaux et al. fail to remedy deficiencies in Keolsch et al. as this reference is also unrelated to antibodies generated by immunization with full length Lng105 recombinant proteins SEQ ID NO:1 or SEQ ID NO:2 or antibodies which compete for binding to the same epitope.

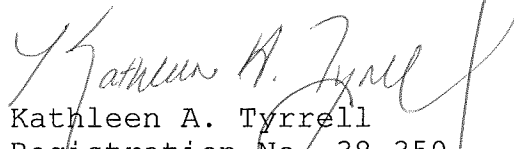
Withdrawal of these rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103 is respectfully requested.

Attorney Docket No.: DEX0499US.NP
Inventors: Fan et al.
Serial No.: 10/593,799
Filing Date: August 6, 2007
Page 17

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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